JUN - 4 1984

Raymond Ragland, Jr., Ph. D.
Director, Regulatory Affairs
Menley & James Laboratories
680 Allendale Road
King of Prussia, PA 19406

Dear Dr. Ragland:

This is in response to your letter addressed to Dr. Lipicky and dated May 16, 1984, in which you forwarded for FDA's review a protocol for a dose-response study to determine the effect of phenylpropanolamine on blood pressure. As you noted, the agency requested data from such studies at meetings with industry on December 2, 1983 and April 11, 1984.

We are considering your submission a "feedback communication" under the OTC Drug Review procedures. Because the protocol was received after closure of the administrative records of the advance notices of proposed rulemaking for cough/cold and weight control drug products, it has not been included in the official administrative record at this time. However, in accordance with the "feedback policy" announced in the FEDERAL REGISTER of September 29, 1981 (46 FR 47740) and further clarified in the FEDERAL REGISTER of April 1, 1983 (48 FR 14050), the protocol will be included in the public record at this time.

The protocol will be included in the administrative records for the respective rulemakings when the administrative records reopen during the comment period following publication of the respective proposed rules.

After completion of our review, we will be in contact with you to arrange a meeting to discuss the protocol.

Sincerely yours,

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drugs and Biologics

76N-052N

LET 89